INGEN ORTHOPEDICS, L.L.C.
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ALM Ortho, Inc.

SEVIIN SHOULDER SYSTEM
Rx Only
Important information for the operating surgeon

DESCRIPTION:
The Ingen SEVIIN Primary Shoulder System includes an individually packaged humeral stem, a metal head and a glenoid component manufactured from ultra-high molecular weight polyethylene. A hemi-shoulder includes the humeral stem and metal head.
The Ingen SEVIIN Reverse Shoulder includes an individually packaged metal humeral cup and a poly inlay manufactured from ultra-high molecular weight polyethylene on the humeral side. The glenoid components include a Titanium Plasma Spray (TPS) coated metaglene plate, a metal glenosphere, and reverse bone screws. These components are intended for use with the SEVIIN Humeral Primary Stems.

INDICATIONS:
Total shoulder or hemi-shoulder replacement is indicted for a severely painful and disabled joint due to osteoarthritis, traumatic or rheumatoid arthritis. The device may also be used for fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from blood supply or where experience indicates that alternative treatment is unsatisfactory. Hemi-shoulder replacement is indicated for un-united or malunited humeral head fractures of avascular necrosis of the humeral head.
Reverse shoulder replacement is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.
The patent's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.
The humeral component is intended for cemented use and the TPS coated metaglene component is intended for cementless use with the addition of screws for fixation.

CONTRAINDICATIONS:
Shoulder arthroplasty is contraindicated in patients with active localized or systemic infections, inadequate bone stock in the operative area which would preclude a successful result, or where poor bone quality would compromise the overall success and result in migration of the components of fracture of the humerus or glenoid. Other relative contraindications relate to absent, irreparable, or nonfunctional rotator cuff or essential muscles.

WARNINGS:
A number of pre-existing conditions can affect the outcome of shoulder arthroplasty. These include: tumors in the operative area, osteoporosis (see contraindications), a history o allergic reactions to cobalt, chromium, nickel or molybdenum, previous tissue reactions to UHMWPE or metallic debris, severe bony deformities which may lead to improper fixation or positioning of the implants, metabolic diseases (i.e. diabetes), prolonged immunosuppressive or steroid therapy, and a history of generalized or local infections.
It is critical that implants from different manufacturers are not used together in an arthroplasty procedure. Specifications are not the same and there is no assurance of a proper fit or tolerances between components.
Implants should never be reused. Previous use may lead to stress risers or other imperfections which would jeopardize performance of the device and it's longevity.
The surgeon should use provisional prosthesis for trials to avoid damaging the device intended for final implantation. Proper handling of all implantable components is critical to the success of total joint replacement.

PRECAUTIONS:
Preoperative planning and surgical techniques are based on principles that provide for sound surgical handling. Complete familiarity of the surgical technique is essential in reverse shoulder arthroplasty. The use of specific surgical instruments is recommended for each operation.
A number of patient conditions could affect the long-term success of shoulder arthroplasty, and the surgeon should consider them carefully. They include active sports participation, the type of labor performed by the patient, alcohol or drug addiction, and the patient's ability to understand and participate in the post-surgical regimen.
Patients should be advised about the limitations and precautions related to shoulder replacement surgery, written instructions should be considered. IT may be advisable to restrict certain activities to preclude loosening of the prosthesis. Patients should be told to report any unusual changes in the operated area as soon as practical. Regular follow-up visits are advised.

ADVERSE EFFECTS:
Premature device failure related to excessive physical activity or trauma has been reported. The most frequently reported adverse effects are as follows, some may not be device-related: early or late loosening of components, infection, device subsidence or subluxation, decreased range of motion absence of external shoulder rotation, damage of the prosthetic components or surrounding tissues, hematoma or delayed would healing, venous thrombosis, cardiopulmonary problems, and continued pain.

STERILITY:

Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.
Sterilization Trays were tested to a sterility assurance level of 10 minus6 using biological indicator (BI) overkill method. *Geobacillus stearothermophilus* was the indicator organism. As there are many variables involved in sterilization, each facility should validate appropriate sterilization cycles (i.e. temperature and times) for the equipment used.

General Care and Handling
Use instruments only for their intended purpose, such as cutting, holding, retracting, torquing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

NOTE: Ensure that the impactor tips included in the tray are disassembled from the impactor handle prior to cleaning.

Cleaning: Follow these steps to thoroughly clean all instruments

1. Submerge instruments in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the instruments for ten (10) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments with a soft sponge and agitate.
3. Use a pipe cleaner or brush in any crevices.
4. Rinse in warm (38-49 degree C) tap water for one (1) minute.
5. Thoroughly flush all instruments and other difficult to reach areas.
6. Ultrasonically clean the instruments for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
7. Rinse the instruments with clean tap water for at least one (1) minute, repeat twice.
8. Dry the instruments thoroughly with a clean, lint free cloth.
9. Visually Inspect instruments for any damage or remaining contaminates. Instruments should be visually clean.
10. Repeat cleaning procedure if necessary if contamination remains. The instrument must be thoroughly clean.
11. Contact ALM Ortho if any instruments are damaged.

Sterilization
Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:
Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time.

MR INFORMATION:
The Ingen SEVIIN Shoulder System has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

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